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## Urgent Field Safety Notice

**Commercial Name of the Affected Product:** Parcan N NaOCl 3% Solution for Canal Irrigation

**FSCA-Identifier:** 2023-06-28

**Inter-Med, Inc. Identifier:** FSCA-RMA 41793 & FSN-RMA 41793

**Type of Action:** Permanent Changes to Instructions for Use (IFU)

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**Date:** 2023-06-28

**Attention:** Septodont Parcan N NaOCl 3% Solution for Canal Irrigation Users

**Type of Device:** 3% NaOCl Irrigation Solution

**Model Name and Number:** 10589L & 10590M, Septodont Parcan N NaOCl 3% Solution for Canal Irrigation

**Lot Number:** Not applicable. Field Safety Notice applies to all Lot Numbers for the Parcan N 3% NaOCl product as the instructions for use is being updated for the Parcan N 3% NaOCl product

### Description of the Problem:

Inter-Med, Inc. was recently notified of a serious incident involving the Parcan N product.

During an endodontic procedure involving the use of Parcan N 3% NaOCl for irrigation of the root canal, the patient experienced swelling of the face (right cheek, lower lip, tongue), heavy swallowing, difficulty breathing, and chest pain. It is suspected that these symptoms were caused by contact of the irrigation solution with unintended tissue through accidental apical extrusion of NaOCl (often referred to as a "sodium hypochlorite accident").

Following notification of this incident, improvements with the Instructions for Use (IFU) were identified pertaining to the prevention and handling of incidents caused by contact of the product with unintended tissue, and specifically with accidental apical extrusion of the product.

*However, it should be noted that there are no issues with the NaOCl irrigant material itself.*



### **Advise on Action to be Taken by the User:**

Use of the device may be continued, taking into consideration the following warnings and precautions that have been added to the Instructions for Use (IFU) which are commensurate with standard dental practice for these types of procedures:

#### Additional Precautions

- Proper treatment planning and establishment of working length is required prior to use of this product.
- Following standard of care, isolate the tooth prior to use of this product to prevent unintended tissue contact or accidental ingestion.
- Properly evacuate the canal during use of this product to prevent unintended tissue contact or accidental ingestion.
- Use of side-vented irrigation tips (27ga or smaller) are recommended for effective distribution of the irrigating solution throughout the root canal, and to minimize the risk of apical extrusion.

#### Additional Warnings

- Over-instrumentation prior to use of this product can result in unintended tissue contact.
- Under-instrumentation prior to use of this product can result in tip binding and subsequent apical extrusion. Do NOT bind the tip in the root canal.
- If tip binding occurs during the procedure, or if resistance is felt during irrigation, discontinue irrigation until the tip binding issue is resolved.
- NEVER use excessive pressure when irrigating NaOCl.
- If apical extrusion of NaOCl has occurred, seek medical attention immediately.
- If ingested, do not induce vomiting. Drink a serving size of water and provide fresh air. Seek medical attention immediately.

Although extremely rare, failure to follow these additional precautions and warnings, in accordance with standard dental care, may result in a higher likelihood of an NaOCl accident / incidental apical extrusion of irrigant.

### **Transmission of this Field Safety Notice:**

An updated copy of the Instructions for Use (IFU) including these added warnings and precautions is also available electronically on Septodont's website.

<https://www.septodont.com/>



This notice needs to be passed on all those who need to be aware within your organisation or to any organisation where the potentially affected devices have been transferred. If applicable, provide details of any affected devices that have been transferred to other organisations to the contact reference person listed below. (If appropriate)

Please transfer this notice to other organisations on which this action has an impact. (If appropriate)

Please maintain awareness on this notice and resulting action for an appropriate period to ensure effectiveness of the corrective action. (if appropriate)

**Contact reference person:**

**Aaron Cooper** | Quality Assurance Manager  
2200 South Street | Racine | WI 53404  
[quality@vista-dental.com](mailto:quality@vista-dental.com) | 262-833-4050

The undersign confirms that the appropriate Regulatory Agency has been notified.



## FSN-RMA 41793 Customer Reply Form

1. Field Safety Notice (FSN) Informaton	
FSN Reference Number	FSN-RMA 41793
FSN Date	2023-06-28
Product/Device Name	Septodont Parcan N NaOCl 3% Solution
Product Code(s)	10589L 10590M
Batch/Serial Number(s)	N/A - FSN applies to the Instructions for Use and is therefore not lot-specific

2. Customer Details	
Healthcare Organisation Name*	
Organisation Address*	
Contact Name*	
Telephone Number*	
Email*	

3. Customer action undertaken on behalf of Healthcare Organisation		
<input type="checkbox"/>	I confirm receipt of the Field Safety Notice and that I read and understood its content.	Customer to complete or enter N/A
<input type="checkbox"/>	The information and updated Instructions for Use (IFU) have been brought to the attention of all relevant users.	Customer to complete or enter N/A
<input type="checkbox"/>	I do not have any affected devices.	Customer to complete or enter N/A
<input type="checkbox"/>	I have a query please contact me	Customer to complete or enter N/A
Print Name*		
Signature*		
Date*		

4. Return acknowledgement to sender
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Email	<a href="mailto:quality@vista-dental.com">quality@vista-dental.com</a>
Postal Address	2200 South St, Racine, WI 53404
Deadline for returning the customer reply form*	2023-10-31

Mandatory fields are marked with \*

It is important that your organisation takes the actions detailed in the FSN and confirms that you have received the FSN.

Your organisation's reply is the evidence we need to monitor the progress of the corrective actions.



## FSN-RMA 41793 Distributor/Importer Reply Form

1. Field Safety Notice (FSN) Information	
FSN Reference Number	FSN-RMA 41793
FSN Date	2023-06-28
Product/Device Name	Septodont Parcan N NaOCl 3% Solution
Product Code(s)	10589L 10590M
Batch/Serial Number(s)	N/A - FSN applies to the Instructions for Use and is therefore not lot-specific

2. Distributor/Importer Details	
Company Name*	
Address*	
Shipping address if different to above	
Contact Name*	
Title or Function	
Telephone number*	
Email*	

3. Return acknowledgement to sender	
Email	<a href="mailto:quality@vista-dental.com">quality@vista-dental.com</a>
Postal Address	2200 South St, Racine, WI 53404
Deadline for returning the distributor/importer reply form	2023-10-31

4. Distributors/Importers (Tick all that apply)		
<input type="checkbox"/>	*I confirm the receipt, the reading and understanding of the Field Safety Notice.	Distributor/Importer to complete or enter N/A
<input type="checkbox"/>	I have checked my stock and quarantined inventory  (NOTE: if stock check revealed no inventory for these products, write 'No remaining inventory' in the field to the right)	Distributor/Importer to enter quantity and date
<input type="checkbox"/>	I have identified customers that received or may have received this device	
<input type="checkbox"/>	I have attached customer list	
<input type="checkbox"/>	I have informed the identified customers of this FSN	Date of communication:



<input type="checkbox"/>	I have received confirmation of reply from all identified customers	
<input type="checkbox"/>	I acknowledge that quarantined inventory may be released for distribution/sale if a copy of FSN-RMA 41793 is provided with the product to customers.	
Print Name*		
Signature*		
Date *		

Mandatory fields are marked with \*

It is important that your organisation takes the actions detailed in the FSN and confirms that you have received the FSN.

Your organisation's reply is the evidence we need to monitor the progress of the corrective actions.