



Urgent Field Safety Notice/ OHUTUSTEATIS

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)

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.

Translation ET:

Probleemi kirjeldus: Inter-Med, Inc. teatas hiljuti tõsisest juhtumist, mis puudutab Parcan N.



Endodontilise protseduuri ajal, kui juurekanali loputamiseks kasutati Parcan N 3% NaOCl, tekkis patsiendil näoturse (parem põsk, alahuul, keel), neelamisraskused, hingamisraskused ja valu rinnus. Arvatakse, et need sümptomid on põhjustatud loputuslahuse kokkupuutest apeksit ümbritseva koega, mis on tingitud juhuslikust NaOCl tungimisest läbi apikaalse avause (mida sageli nimetatakse "naatriumhüpokloriti õnnetuseks").

Pärast seda juhtumit tehti kasutusjuhiste (IFU) täiustused, mis on suunatud sarnaste intsidentide ennetamisele ja ohjamisele, mis võivad tekkida loputuslahuse soovimatul kokkupuutel koega, eelkõige loputuslahuse juhusliku läbitungimisega läbi hamba apikaalse avause.

Siiski tuleb märkida, et NaOCl loputuslahuse endaga pole probleemi.

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.

Translation ET:

LISA-ETTEVAATUSABINÕUD: Enne selle toote kasutamist on vajalik nõuetekohane protseduuri ettevalmistamine ja kanali tööpikkuse määramine. Kindlasti tuleb kontrollida kanalitipu suletust.

- Järgides protseduuri standardit, isoleerige hammas koferdamiga enne selle toote kasutamist, et vältida loputuslahuse soovimatut kokkupuudet kudedega või juhuslikku allaneelamist.
- Toote kasutamise ajal (loputamise ajal) tühjendage kanal korralikult aspiratsiooni teel, et vältida lahuse soovimatut kokkupuudet kudedega või lahuse juhuslikku allaneelamist.
- Loputuslahuse tõhusaks jaotamiseks kogu juurekanalis ja lahuse väljapressimise ohu minimeerimiseks läbi apeksi on soovitatav kasutada lateraalsete avadega loputusotsikuid (27 ga või väiksemaid).

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.

Translation ET:

LISA- HOIATUSED:

- Ülemäärane instrumenteerimine enne loputuslahuse kasutamist võib põhjustada loputuslahuse soovimatut kokkupuudet kudedega.
- Liiga vähene instrumenteerimine enne loputuslahuse kasutamist võib põhjustada loputusotsiku kinnitumist ja sellele järgnevat apikaalset ekstrusiooni. ÄRGE kinnitage loputusotsikut juurekanalis..
- Kui protseduuri ajal loputusotsik kinnitub või kui loputamise ajal tunnete vastupanu, katkestage loputamine, kuni otsiku kinnitumise probleem on lahendatud.
- ÄRGE kunagi kasutage NaOCl loputamisel liigset survet.
- Kui on toimunud NaOCl apikaalne ekstrusioon, pöörduge viivitamatult arsti poole.
- Allaneelamisel ärge kutsuge esile oksendamist. Jooge suur kogus vett ja tagage värske õhk. Pöörduge viivitamatult arsti poole.

Kuigi see on äärmiselt haruldane, võib täiendavate ettevaatusabinõude ja hoiatuste mittejärgimine vastavalt tavapärasele hambaravile kaasa tuua suurema tõenäosusega NaOCl õnnetuse / irrigandi juhusliku apikaalse väljapressimise.

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 organization or to any organization where the potentially affected devices have been transferred. If applicable,



provide details of any affected devices that have been transferred to other organizations to the contact reference person listed below. (If appropriate)

Please transfer this notice to other organizations 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)

Translation ET:

OHUTUSTEATISE EDASTAMINE

Kasutusjuhendi (IFU) uuendatud koopia, mis sisaldab ülalloetletud lisa-hoiatusi ja lisa-ettevaatusabinõusid, on samuti elektrooniliselt saadaval Septodonti veebisaidil. <https://www.septodont.com/>

Ohutusteatis Parcan N lõputuslahuse kohta tuleb edastada kõikidele raviasutustele, kuhu toode/ tooted on tarnitud.

Olge kindel, et raviasutused, kuhu Parcan N toode on tarnitud, oleks teadlikud lõputuslahuse turvalisest kasutamisest selle ohutusteatise kättesaamise hetkest sobiva aja jooksul, et patsiendi turvalisus oleks tagatud.

Contact reference person:

Aaron Cooper | Quality Assurance Manager
2200 South Street | Racine | WI 53404
quality@vista-dental.com | 262-833-4050

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